

# DataLabs Speeds Merck Pharmaceutical Products to Market Using Microsoft Visio Diagrams and Database Integration

## Microsoft Visio Case Study

September 2002

Pharmaceutical companies lose approximately one million dollars each day a product is clinically tested instead of sold on the market, so expediting clinical trials, while still maintaining quality, is critical to companies, such as Merck—a leading pharmaceutical company that discovers, develops, tests, manufactures, and markets its own products. In an effort to expedite and optimize its clinical trials, Merck is implementing DataLabs CTMS (Clinical Trial Management System) and assisting the Clinical Data Interchange Standards Committee (C-DISC) in developing clinical trial standards. On behalf of Microsoft® Corporation, META Group Consulting recently conducted interviews with Merck executives, DataLabs employees, Microsoft employees, and members of C-DISC to determine the diagramming needs of pharmaceutical companies and how DataLabs CTMS, which incorporates the Microsoft Visio® diagramming platform, meets those specialized needs, thereby accelerating the time-to-market cycle for pharmaceutical products and maximizing profits for pharmaceutical companies.

### Pharmaceutical companies need to simplify and expedite clinical trial processes to speed products to market

Pharmaceutical companies are typically conservative and resistant to change; however, Merck breaks that mold. Merck is an innovative, research-driven pharmaceutical company that is globally recognized for conducting high-quality clinical trials on its pharmaceutical products by using state-of-the-art technology and applying rigorous scientific and ethical standards. Pharmaceutical companies, such as Merck, face the unique challenge of balancing these high-quality clinical tests with the discovery of new pharmaceutical drugs.

Pharmaceutical drug patents are typically valid for 20 years, but before any pharmaceutical drug goes to market, it must typically undergo 10–15 years of clinical testing—a resource-intensive process that involves millions of documents, numerous clinical trials, and hundreds of millions of dollars—to get FDA approval and make sure the drugs are safe. The longer and more expensive these clinical trials are, the fewer new drug discoveries pharmaceutical companies can investigate.

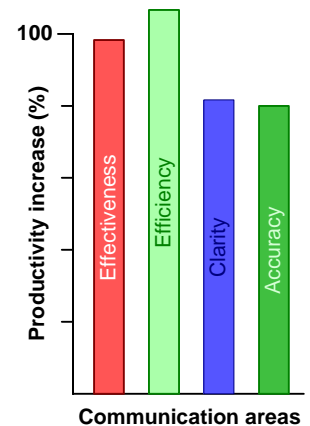
Not only are these tests lengthy and expensive, the processes are manual, disjointed, cumbersome, and paper-intensive. They currently incorporate no industry standards for designing or conducting trials and include no standard tools for integrating trial tasks and data. At the end of each test, the pharmaceutical company is left with only roughly five years of product patent protection before generic drugs appear on the market. As a result, pharmaceutical companies are under intense pressure to expedite clinical trials, thereby streamlining the time-to-market cycle for their products.



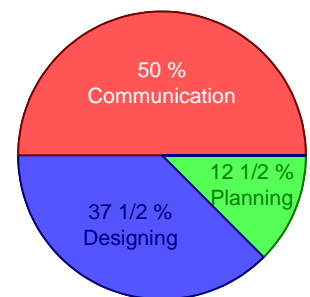
### Interview findings

The following information applies to those interviewed at Merck.

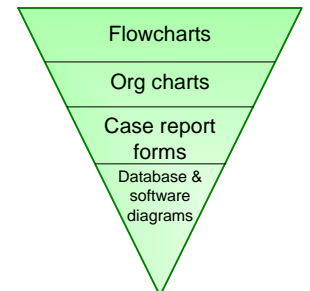
#### Projected productivity increases



#### Most critical areas of value for Microsoft Visio



#### Microsoft Visio diagrams used most often



## ***Merck leads pharmaceutical companies in adopting state-of-the-art technology to expedite clinical trial processes***

Merck is responding to this pressure by working closely with C-DISC to develop clinical trial standards and strategically with DataLabs—a biopharmaceutical software company and Microsoft Certified Provider—to develop and conduct clinical trials using its integrated clinical trial management solution, DataLabs CTMS, which uses Microsoft Visio as its visual front-end. Microsoft Consulting Services has also been working with DataLabs and Merck to integrate DataLabs CTMS with Microsoft Visio, the .NET™ platform, and other back-end systems. Managing Consultant for Microsoft Consulting Services, Janice Armandi says this about their endeavors: “Microsoft Consulting Services is working to integrate the front-end data capture with the back-end framework and custom services. The focus is on streamlining the process of conducting clinical trials and accurately propagating the data to other systems. Visio allows anyone to very quickly provide detailed information to a client or audience. It is very user friendly, and with it, you can easily capture information—a picture is worth a thousand words.” Vice President of Microsoft Consulting Services, David Lubinski predicts the Microsoft Visio diagramming capabilities alone in DataLabs CTMS will eliminate 3–4 years of the time-to-market cycle for pharmaceutical drugs, which in turn will enable pharmaceutical companies to allocate more time and resources to new drug discoveries.

META Group Consulting recently interviewed twelve people involved in this streamlining effort—three Merck executives, three Microsoft employees, three DataLabs employees, two C-DISC members, and one Merck consultant—to determine how pharmaceutical companies can use the Microsoft Visio diagramming capabilities in DataLabs CTMS to meet their diagramming needs. They found pharmaceutical companies can use Microsoft Visio to communicate ideas, information, and systems, in addition to more specialized tasks. Merck, for example, can create custom shapes for its clinical trial diagrams that support the emerging C-DISC standards, case report forms that facilitate data collection, and database models directly from case report forms—all of this while still meeting FDA regulatory requirements.

## ***Merck forecasts saving time and increasing efficiency using DataLabs CTMS and Microsoft Visio diagrams***

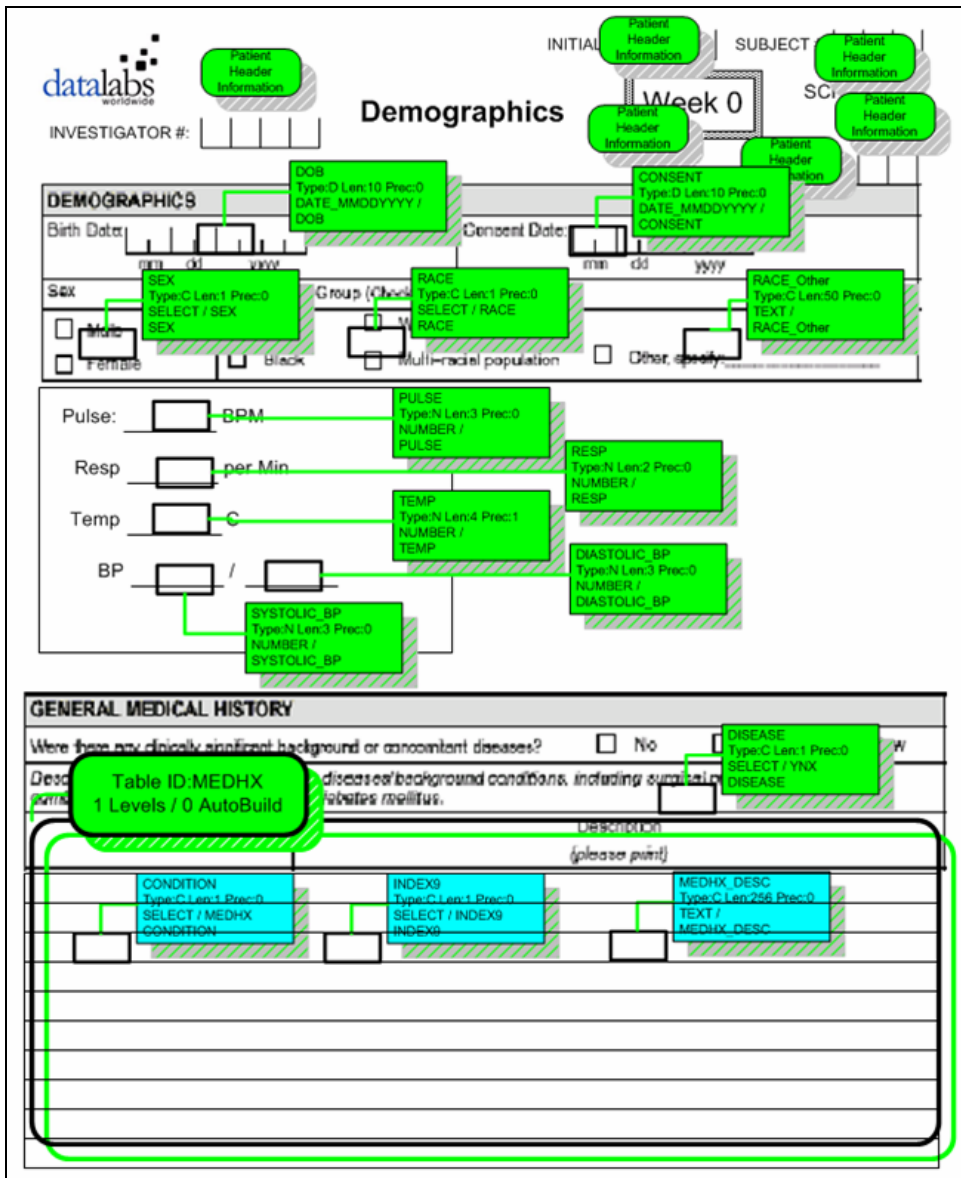
Scott Thompson, Vice President of Enterprise Development for DataLabs, saves an average of 120 hours and is 200% more efficient by using the Microsoft Visio diagramming capabilities in DataLabs CTMS to create case report forms. This task typically takes Merck as long as eight weeks. However, using Microsoft Visio, Mr. Thompson predicts Merck will be able to design case report forms in five days, and as a result, Merck will be able to launch trials more quickly. These predictions are supported by Merck interviewees who predict they'll save 63 hours per month using Microsoft Visio shapes to create case report forms. Acting Manager and Senior Technical Specialist at Merck, Stephen Fischer, says, “Visio enables us to visually design and implement a clinical study. It significantly cuts the time to design studies.”

In the early stages of clinical trial design, design teams must first determine the clinical trial organization, the type of customer data they want to collect, and the data format they want to use. Designers can use the Microsoft Visio shapes in DataLabs CTMS to represent the case report forms—the primary mechanism for collecting clinical trial data—and the shape sequence to develop the data collection process. After the design teams organize the clinical trial process, they can move on to designing the case report forms using Microsoft Visio Forms shapes to illustrate the order in which they want to collect patient data and the type of patient data they want to gather.



## Merck predicts efficient database implementation using DataLabs CTMS and Microsoft Visio database integration

Once the case report forms have been designed, designers annotate the reports using custom Microsoft Visio shapes to specify the details of the database implementation, including descriptions, data types, indexes, and other information. The annotated forms provide not only a detailed record of the system used to support the clinical trial, but also a basis for seamlessly generating the database in Microsoft Access or Microsoft SQL Server™, for example. The data, or custom properties, stored with each of the custom Microsoft Visio shapes is exported to XML file format and is used to automatically generate the database tables, entry forms, and export functions.



Designers can annotate case report forms with database shapes to generate the patient information database structure.

Merck interviewees predict saving as much as 20 hours per month creating database diagrams using Microsoft Visio diagramming capabilities. They also predict a 98%

increase in effectiveness, a 117% increase in efficiency, an 81% increase in clarity, and an 80% increase in accuracy.

Rich Gleeson, Vice President of Enterprise Consulting at DataLabs says, “Visio is the easiest part to train client companies on; form designers and data managers developing protocols get it. Merck has a huge proprietary legacy system. Using the DataLabs/Visio solution will enable easier trial design and implementation. It will also integrate into Merck databases and help them facilitate standards implementations, such as C-DISC and FDA reporting requirements.” Rebecca Kush, President of C-DISC adds, “Visio is a powerful tool that will be an important platform for the electronic capture of data for clinical trials. It will help insure that accurate data will be collected and comply with evolving industry standards. It will also help in the FDA approval process and in regulation compliance.”

## ***Pharmaceutical companies also communicate ideas, information, and systems using Microsoft Visio diagrams***

In addition to these specialized diagramming needs, pharmaceutical companies have many of the same diagramming needs as other healthcare organizations. They all use the wide variety of diagramming solutions provided with Microsoft Visio—flowcharts, organization charts, block diagrams, timelines and calendars, and more—to clearly define and communicate ideas, information, and systems.

Business healthcare professionals, such as project managers publish timelines and incorporate them into clinical trial specifications to clearly communicate key dates to team members. Administrators use organization charts to convey organizational hierarchies that may be critical in getting approval for a new trial. Clinicians share timelines with subjects following treatment so the patients can clearly visualize recovery milestones and have realistic expectations for their recovery process.

Microsoft Visio also helps pharmaceutical companies and other healthcare organizations manage assets effectively. Technical healthcare professionals diagram and document ideas, information, and systems to manage patient data, facilitate IT deployments, and document facilities layouts and engineering plans. For example, IT professionals diagram network topologies in order to track assets and prepare for an operating system migration. Facilities managers can use floor plans to track and manage physical assets at clinical trial sites.

The Merck interviews show flowcharts are shared with as many as 100 people, database diagrams, software diagrams, and floor plans with as many as 30 people, project diagrams as many as 25 people, network diagrams, directory service diagrams, Web site maps, and organizational charts with as many as 12 people, and block diagrams with as many as 8 people. All of these diagrams, including the more specialized case report forms and database model diagrams, help pharmaceutical companies communicate information in a way that is concise, memorable, and universal—to help scientists, clinicians, physicians, nurses, patients, and colleagues understand each other and work together to develop the best possible medicines, speed them to market, and save and improve countless lives worldwide.

## ***Additional Information***

For the latest Microsoft Visio product information, visit [www.microsoft.com/office/visio/](http://www.microsoft.com/office/visio/).

The interviews referenced in this document were conducted by META Group Consulting on behalf of Microsoft Corporation. The statements within this document report interview findings and offer insight into Microsoft Visio product usage, however, the qualitative statements are not made by META Group Consulting. These interview findings and statements do not represent a statistically valid sample and do not endorse Microsoft Corporation, its products, or services.

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